HED Records Center Series 361 Science Reviews - File R084355 - Page 1 of 2



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JU17 6 1990

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT:

Dicamba (029801). Registrant Response to Ruminant and Hen Metabolism

Studies. GDLN 171-4b.

DP Barcode:D226526; CBRS No. 17271; No MRID No.

FROM:

David J. Miller, HSO, U.S. Public Health Service

Chemistry Pilot Review Team

Chemistry Branch II - Reregistration Support

Health Effects Division (7509C)

THROUGH: Edward Zager, Branch Chief

Chemistry Branch II - Reregistration Support

Health Effects Division (7509C)

TO:

Paula Deschamp, Section Head

Reregistration Section

Risk Characterization and Analysis Branch

Health Effects Division (7509C)

The registrant previously submitted ruminant and poultry metabolism studies which were judged by CBRS to be adequate pending submission of dates of sample collection, extraction and analysis (L. Cheng, 3/7/96, CBRS No. 13874; DP Barcode D204482). The review concluded that frozen storage stability data could be required for samples that had been stored for more than 6 months prior to analysis.

The registrant has recently submitted a letter dated May 6, 1996 (J.E. Bryant, Sandoz Agro to J. Mitchell, USEPA) which included this information as an attachment. The data show that in no case were samples stored for longer than 6 months (from date of collection) prior to preliminary TLC analyses. All confirmatory (HPLC and MS) analyses were performed within 9 months of sample collection. CBRS concludes that there are no storage stability concerns associated with the previously submitted metabolism studies (MRIDs 43245201 and 43245202) therefore that GDLN 171-4(b) relating to the nature of the residue in ruminants and poultry is satisfied; no further data are required. Per the L. Cheng review, the residue to be regulated in animals consists of dicamba and 3,6-dichloro-2-hydroxybenzoic acid.

The L. Cheng review also required that samples from the metabolism studies be analyzed

using AM-0685 as part of the requirement that any proposed analytical enforcement method be radiovalidated. The registrant has responded that these reports have now been submitted (MRIDs 43461701 relating to new method validation and 43554205 relating to confirmation of residues using the enforcement analytical method). CBRS has confirmed that these studies are presently in-house awaiting review.

RDI: Pilot Team:6/18/96;RPerfetti:6/20/96;EZager:6/24/96.cc: RF, SF, List A Rereg. F., J. Mitchell (SRRD), DJM.